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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,121	07/02/2003	Jamie L. Brewer	260385.20005	6561

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EXAMINER	
JUEDES, AMY E	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,121	BREWER ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-14,17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-16 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 5/7/07 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/7/07 has been entered.

Claim 15 has been amended.
Claim 19 has been added.
Claims 1-19 are pending.

Claims 1-14 and 17-18 stand withdrawn from further consideration pursuant to 37 CFR 1.14209 as being drawn to a nonelected invention.

Claims 15-16 and 19 are under examination.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-16 stand rejected, and claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinella et al., 1994, in view of Wei et al., 1994 and US patent 6,017,699 (of record).

As set forth previously, Spinella et al. teach that analysis of TCR gene expression, particularly by PCR, is becoming increasingly important to a variety of clinical programs (see pg. 111 in particular). Spinella et al. further teach employing a standard reference template in the PCR that consists of cloned TCR genes of the 24 known TCR Vβ families (i.e. Vβ 1-24, see pg. 114 and Fig. 9.3, in particular). Spinella et al. further teach that including the reference templates is extremely important since it helps to ensure the accuracy of the analysis (see pg. 115, in particular). Furthermore, said reference template comprising the cloned genes of Vβ1-Vβ24 would comprise SEQ ID NO: 33-54, since these represent DNA fragments derived from Vβ1-Vβ24 TCR V regions.

Spinella et al. do not teach the TCRVβ25 gene, or a kit comprising the reference templates, an enzyme, buffer solutions, and deoxynucleotide triphosphates.

Wei et al. teach the identification of a new TCRVβ gene segment, Vβ25 (see Fig. 1 in particular).

The '699 patent teaches that reagents necessary for performing an assay can be packaged in a kit as a matter of convenience (see column 6 in particular). The '699 patent also teaches that kits can comprise quantification reagents, including PCR reagents such as buffers, enzymes, and nucleoside triphosphates (see column 7 in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add the gene encoding the TCR Vβ25 region, as taught by Wei et al., to the standard reference template set comprising the TCR Vβ1-24 genes taught by Spinella et al. The ordinary artisan at the time the invention was made would have been motivated to do so, since Spinella et al. teach that a reference template comprising the Vβ genes of all the known Vβ families is extremely important since it helps to ensure the accuracy of TCR analysis, and Wei et al. teach that Vβ25 is a newly identified TCR Vβ gene. Furthermore, the ordinary artisan would have been motivated to package the reagents necessary for performing the PCR reaction (an enzyme, buffers, and deoxynucleotide triphosphates), as taught by the '699 patent, along with the reference template made obvious by Spinella et al. and Wei et al. The ordinary artisan at the time the invention was made would have been motivated to do so since the '699 patent teaches that reagents necessary for performing an assay can be packaged in a kit as a matter of convenience. Furthermore, said reference template comprising the cloned genes of Vβ1-Vβ25 would comprise SEQ ID NO: 33-55, since these represent DNA fragments derived from Vβ1-Vβ25 TCR V regions.

Applicants arguments filed 5/7/07 have been fully considered, but they are not persuasive.

Applicant argues that the disclosure by Spinella of the cloned TCR genes corresponding to each of the 24 known TCR Vβ families is too general and does not specifically disclose SEQ ID Nos: 35-55.

However, the instant claims are drawn to a kit "consisting essentially of" SEQ ID Nos: 33-55. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." (see MPEP 2111.03) The entire cloned gene of said Vβ1-Vβ24 comprises SEQ ID Nos: 33-54.

Applicant further argues that the TCR Vβ25 gene taught by

Wei et al. is over 960 nucleotides long, and is not the same as the instant nucleic acids which are at most 25 nucleotides long.

However, the instant claims are drawn to a kit "consisting essentially of" (i.e. comprising) SEQ ID Nos 33-55. The nucleic acid sequence taught by Wei et al. comprises SEQ ID NO: 55 (see residues 589-611 in Fig. 1 of Wei et al.).

3. The following are new grounds of rejection.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-16 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is insufficient written description to demonstrate that applicant was in possession of the claimed genus of "variations" of SEQ ID NOs: 33-55 that differ by "no more than 8 nucleotides" or "no more than 2 nucleotides".

The instant claims encompass a genus of nucleic acid variants that differ by up to 8 nucleotides from the sequences of SEQ ID NOs: 33-55. The sequences of SEQ ID NOs: 33-55 comprise as few as 18 nucleotides. Thus, the instant claims encompass structurally different "variations" that differ by up to approximately 40% from the sequences of SEQ ID NO: 33-55. Furthermore, even when the claims are limited to variations of no more than 2 nucleotides, this still encompasses structurally different sequences varying up to approximately 10% from the sequences of SEQ ID NOs: 33-55. Additionally, the claims do not specify any functional limitations required of the claimed sequences, and thus the claims might encompass functionally different "variations" that do not even function to assess the expression of T cell receptor variable subunits. Furthermore, the instant specification does not disclose a single species of sequence that is a "variation" of SEQ ID NOs: 33-55. Thus, one of skill in the art would conclude that the specification fails

to provide adequate written description to demonstrate that Applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F. 3d 1559, 43, USPQ2d 1398.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner
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6/14/07
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER